IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Atul D. AYER, et al

Serial No: to be assigned

Filed:

September 12, 2003

For:

THERAPEUTIC COMPOSITION

AND DRUG DELIVERY SYSTEM FOR ADMINISTERING DRUG

Mail Stop Patent Application Commissioner for Patents P. O. Box 1450 Alexandria, V. A. 22313 Group Art Unit: 3763

Examiner: MENDEZ, Manuel A.

SUBSPECE PSEV3

EXPRESS MAIL CERTIFICATE

"Express Mail" label number: EV 324 303 928 US

Date of Deposit: September 12, 2003

I hereby state that the following attached paper(s) or fee(s):

Patent Application and supporting documentation

- 1. Utility (Continuation) Patent Application Transmittal (PTO/SB/05) (2 pages);
- 2. Fee Transmittal for FY 2003 (PTO/SB/17) and Patent Application Fee Determination Record (PTO/SB/06); (2 pages, in duplicate);
- 3. Petition for an Extension of Time Under 37 CFR 1.136(a) (PTO/SB/22) (1 page, in duplicate);
- 4. Preliminary Amendment (3 pages);
- 5. Application specification, including claims pages and abstract; (24 pages);
- 6. Formal Drawings (2 Sheets);
- 7. Declaration and Power of Attorney (4 pages, from Previous Application);
- Revocation of Power of Attorney and Appointment of New Power of Attorney (PTO/SB/82) with Certificate under 37 CFR §3.73(b) (PTO/SB/96) and copy of assignment (6 pages); and
- 9. Return Postcard.

Are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. section 1.10, on the date indicated above and is addressed to the Commissioner for Patents, Alexandria, V. A. 22313.

Susan Ahearn

Signature of person mailing paper or fee

Complete if Known

PTO/SB/17 (08-03)

Approved for use through 07/31/2006. OMB 0651-0032

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

FEE TRANSMITTAL for FY 2003 Effective 010172003. Patent fees are subject to annual revision Applicant claims small entity status. See 37 CFR 1.27 TOTAL AMOUNT OF PAYMENT (check all that apply) METHOD OF PAYMENT (check all that apply) Check Credit card Monay Other None Deposit Account: Deposit Johnson & Johnson The Commissioner is authorized tic (check all that apply) The Commissioner			T	J V VI	NA 2	ITTA	g l				Co	mplete	if Known	<u> </u>	
First Named Inventor	l Li		1 [7414			느	Appli	cation	Numb	er				
### Applicant claims small entity status. See 37 CFR 1.27 TOTAL AMOUNT OF PAYMENT (check all that apply) METHOD OF PAYMENT (check all that apply) Method OF PAYMENT (check all that apply) Check Gradit card Money Other None Order Other None Order Other Oth	ł	13		Filing	iling Date			September 12, 2003							
Applicant claims small entity status. See 37 CFR 1.27 TOTAL AMOUNT OF PAYMENT (s) 2,184.00 At Unit Atomorp Docket No. AR02766USACON2 METHOD OF PAYMENT (chock all that apply) FEE CALCULATION (continued) Check Credit card Money Other None Other Total Code (s)	Effectiv			First	irst Named Inventor			Atul D	. AYER						
Name								Examiner Name to be assi			assigned	<u>t</u>			
METHOD OF PAYMENT (chock all that apply) Check Credit card Money Other None Critical Money Other None Critical Charles (Code (s) Supposed Number Previously in the Control of Critical Charles (Code (s) Supposed Number Previously in the Code								A DOOTCOLIC A CONIG				CONO			
Check Credit card Money Other None Surge Entity Small Entity	TOTAL AI	WOON!	OF PA	INENI	<u> (Φ)</u> Δ	2,164.00	1	Attorney Docket No. ARUZ/00USACUINZ							
Supposit Account															
Deposit Account			t card		Oth	er None					_				
10-0750 1051 130 1052 130 1052 130 1053 130		Account:										Fee I	Description	n	
Deposit Account Johnson & Johnson Johnso	Account		10-0750						l		Curabi		•		Fee Paid
The Commissioner is authorized to: (check all that apply) Moremy (seles) indicated below Moremy (seles) indicated below Moremy (seles) indicated below More (seles) indicated below Moremy (seles) indicated below (scapt for the filing fee to the above-dentified deposit account. FEE CALCULATION 1251 110 1251 151 1251 55 Extension for reply within first month 1252 410 1252 205 Extension for reply within first month 1252 410 1253 930 1253 485 Extension for reply within first month 1252 410 1255 1,970 1255	Deposit		رها ما						1			-	-		
Mathematics	Account Johnson & Johnson							 		cover	sheet		g 100 01		
Charge free(s) indicated below. except for the filing fee 1805 1,840 1805 1,8									ľ			• .		te reexamination	
Charge feets indicated below, except for the filing fee to the above-identified deposit account. 1805 1,840*									1	,		•	•		
Table Tabl									!		Exami	ner action	1	•	
1. BASIC FILING FEE 1253 110 2251 55 Extension for reply within first month 1252 110 2252 205 Extension for reply within second month 1252 110 2252 205 Extension for reply within second month 1253 110 2252 205 Extension for reply within second month 1253 110 2252 205 Extension for reply within formth 1253 110 2252 205 Extension for reply within from th 1253 110 2252 205 Extension for reply within from th 1253 110 2252 1255							1805	1,840*	1805	1,840*				R after	
1. BASIC FILING FEE Large Entity Small Entity Fee Paid 1252 410 1252 410 1253 393 2253 465 Extension for reply within fourth month 1254 1,450 1,							1251	110	2251	55	Exten	sion for re	ply within fire	st month	
Fee	1. BASIC FI						1252	410	2252	205	Exten	sion for re	eply within se	cond month	000.00
Code (\$) Code (\$)	Large Entity S	Small Ent	ity				1253	930	2253	465	Exten	sion for re	eply within thi	rd month	930.00
1002 330 2002 165 Design filing fee 1401 320 2401 160 Notice of Appeal 1402 320 2402 160 Filing brief in support of an appeal 1403 280 2403 140 Request for oral hearing 1452 110 1451 1,510 Reguest for oral hearing 1451 1,510 Reguest for oral hearing 1452 110 1452 110 1452 110 1452 110 1452 110 1453 1,300 2453 650 Petition to revive - unavoidable 1453 1,300 2453 650 Petition to revive - unavoida				ee Descriptio	<u>n</u>	Fee Paid	1254	1,450	2254	725	Exten	sion for re	eply within for	urth month	
1003 300 2002 165 Design filing fee 1402 320 2401 160 Notice of Appeal 1403 320 2402 160 Filing brief in support of an appeal 1403 320 2403 140 Request for oral hearing 1403 280 2403 140 Request for oral hearing 1451 1,510 1451 1,510 Petition to institute a public use proceeding 1452 1501 1,300 2501 650 Design issue fee 1501 1,300 2501 650 Design issue fee 1501 1,300 2501 650 Design issue fee 1503 630 2503 315 Plant issue fee 1503	1001 750	2001 37	5	Utility filing fe	е	750 00	1255	1,970	2255	985	Exten	sion for re	eply within fift	h month	
1004 750 2004 375 Reissue filing fee 1403 280 2403 140 Request for oral hearing 1451 1,510 1451 1,510 1451 1,510 Petition to institute a public use proceeding 1451 1,510 1451 1,510 Petition to revive - unavoidable 1453 1,300 2453 650 Petition to revive - unintentional 1453 1,300 2453 650 Petition to	1002 330	2002 16	5	Design filing	ee	7 30.00	1401	320	2401	160	Notice	of Appea	el .		
1451 1,510 145	1003 520	2003 26	0	Plant filing fee	e		1402	320	2402	160	Filing	brief in su	ipport of an a	ppeal	
SUBTOTAL (1) (\$) 750.00 1452 110 2452 55 Petition to revive - unavoidable 1453 1,300 2453 650 Petition to revive - unintentional 1453 1,300 2453 650 Petition to revive - unintentional 1501 1,300 2501 650 Utility issue fee (or reissue) 1502 470 2502 235 Design issue fee 1503 630 2503 315 Plant issue fee 1503 630 2503 315 Plant issue fee 1460 130 Petitions to the Commissioner 1460 130	1004 750	2004 37	5	Reissue filing	fee		1403	280	2403	140	Reque	est for oral	l hearing		
2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE Fee from Fee Paid Independent 1	1005 160	2005 8	0	Provisional fil	ing fee		1451	1,510	1451	1,510	Petitio	n to institu	ute a public ι	se proceeding	
2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE Fee from below Fee Paid 11 -20** = 0 X		!	SU	BTOTAL (1) (\$) 7	50.00	1452	110	2452	55	Petitio	n to revive	e - unavoidat	ole	
Total Claims	2 FYTRA (CL AIM I	FFFS	FOR LITH	ITV ANI	PEISSUE	i	•	2453	650	Petitic	n to reviv	e - unintentic	nal	
Total Claims Independent	L. LATION				Fee fro	m			ı		_				
Independent 9 -3** 6 X 84 = 504 1460 130 1460 130 1460 130 Petitions to the Commissioner 1807 50 1807 50 Processing fee under 37 CFR 1.17(q) 1807 50 1807 50 Processing fee under 37 CFR 1.17(q) 1807 50 1807 50 Processing fee under 37 CFR 1.17(q) 1807 50 1807 50 Processing fee under 37 CFR 1.17(q) 1807 50 1807 50 Processing fee under 37 CFR 1.17(q) 1807 50 1807 50 Processing fee under 37 CFR 1.17(q) 1807 50 1807 50 Processing fee under 37 CFR 1.17(q) 1807 1807 1807 1807 1807 1808 1808 1808 1808 1808 1808 1808 1808 1808 1809 18	Total Claims	[11]							ļ		_		е	İ	
Multiple Dependent Large Entity Small Entity Small Entity Fee Fee Fee Fee Code (\$) Code (\$) 1202	Independent	لتنتا							ľ						
Large Entity Small Entity Fee Fee Fee Fee Fee Fee Fee Fee Fee Fee Code (\$) 1202 18 2202 9 Claims in excess of 20 1201 84 2201 42 Independent claims in excess of 3 1203 280 2203 140 Multiple dependent claim, if not paid 1204 84 2204 42 ** Reissue independent claims over original patent 1205 18 2205 9 ** Reissue claims in excess of 20 1205 18 2205 9 ** Reissue claims in excess of 20 1206 1809 750 2809 375 Filing a submission after final rejection (37 CFR 1.129(a)) 1207 2810 375 For each additional invention to be examined (37 CFR 1.129(b)) 1208 1809 750 2810 375 For each additional invention to be examined (37 CFR 1.129(b)) 1204 84 2204 42 ** Reissue claims in excess of 20 1205 18 2205 9 ** Reissue claims in excess of 20 and over original patent 1806 180 1806 180 Submission of Information Disclosure Stmt 8021 40 8021 40 Recording each patent assignment per property (times number of property (times number of properties) 1809 750 2809 375 Filing a submission after final rejection (37 CFR 1.129(a)) 1810 750 2810 375 For each additional invention to be examined (37 CFR 1.129(b)) 1809 750 2810 375 For each additional invention to be examined (37 CFR 1.129(b)) 1809 750 2810 375 For each additional invention of a design application 1800 750 2810 375 For each additional invention to be examined (37 CFR 1.129(b)) 1809 750 2810 375 For each additional invention to be examined (37 CFR 1.129(b)) 1809 750 2810 375 For each additional invention to be examined (37 CFR 1.129(b)) 1800 750 2810 375 For each additional invention to be examined (37 CFR 1.129(b)) 1800 750 2810 375 For each additional invention of a design application 1801 750 2801 375 For each additional invention of a design application 1801 750 2801 375 For each additional inventi			•			i <u></u>									
Fee Fee Code (\$) 1202 18 2202 9 Claims in excess of 20 1201 84 2201 42 Independent claims in excess of 3 1203 280 2203 140 Multiple dependent claims over original patent sover original patent 1205 18 2205 9 ** Reissue claims in excess of 20 and over original patent SUBTOTAL (2) (\$) 504.00 **or number previously paid, if greater; For Reissues, see above SUBMITTED BY Registration No. (Attorney/Agent) Registration No. (Attorney/Agent) Registration No. (Attorney/Agent) Registration No. (Attorney/Agent) Recording each patent assignment per property (times number of properties) 1802 140 8021 40 8021 40 Recording each patent assignment per property (times number of properties) 1809 750 2809 375 Filing a submission after final rejection (37 CFR 1.129(a)) 1809 750 2810 375 For each additional invention to be examined (37 CFR 1.129(b)) 1801 750 2801 375 Request for Continued Examination (RCE) 1802 900 1802 900 Request for expedited examination of a design application Other fee (specify) *Reduced by Basic Filing Fee Paid **Reduced by Basic Filing Fee Paid **Complete (#applicable) **Reduced by Basic Filing Fee Paid **Complete (#applicable) **Telephone 650-564-5171	Large Entity	Small F	ntity									•		`''	
1202 18 2202 9 Claims in excess of 20 1201 84 2201 42 Independent claims in excess of 3 1203 280 2203 140 Multiple dependent claims in operation (37 CFR 1.129(a)) 1204 84 2204 42 ** Reissue independent claims over original patent over original patent (1205 18 2205 9 ** Reissue claims in excess of 20 and over original patent (\$\frac{1}{3}\$) 504.00 **or number previously paid, if greater; For Reissues, see above Registration No. (Attorney/Agent) Registration No. (Attorney/Agent) Registration No. (Attorney/Agent) Registration No. (Attorney/Agent) Telephone 650-564-5171	Fee Fee	Fee	Fee	Fee Desci	iption										
1201 84 2201 42 Independent claims in excess of 3 1203 280 2203 140 Multiple dependent claims in excess of 3 1204 84 2204 42 ** Reissue independent claims over original patent over original patent of and over original patent 1205 18 2205 9 ** Reissue claims in excess of 20 and over original patent SUBTOTAL (2) (\$) 504.00 **or number previously paid, if greater; For Reissues, see above SUBMITTED BY Registration No. (Attorney/Agent) Registration No. (Attorney/Agent) 1809 750 2809 375 Filing a submission after final rejection (37 CFR 1.129(a)) 1810 750 2810 375 For each additional invention to be examined (37 CFR 1.129(b)) 1801 750 2810 375 Request for Continued Examination (RCE) 1802 900 1802 900 Request for expedited examination of a design application Other fee (specify) *Reduced by Basic Filing Fee Paid SUBTOTAL (3) (\$) 930.00 SUBMITTED BY Registration No. (Attorney/Agent) Registration No. (Attorney/Agent) Registration No. (Attorney/Agent)		ì		Claims in ev	ness of 20		8021	40	8021	40		. 7.	, ,	'\	
1203 280 2203 140 Multiple dependent claim, if not paid 1204 84 2204 42 ** Reissue independent claims over original patent 1205 18 2205 9 ** Reissue claims in excess of 20 and over original patent SUBTOTAL (2) (\$) 504.00 **or number previously paid, if greater; For Reissues, see above SUBMITTED BY Registration No. (Attorney/Agent) 1810 750 2810 375 For each additional invention to be examined (37 CFR 1.129(b)) 1801 750 2801 375 Request for Continued Examination (RCE) 1802 900 1802 900 Request for expedited examination of a design application Other fee (specify) *Reduced by Basic Filing Fee Paid SUBTOTAL (3) (\$) 930.00 Registration No. (Attorney/Agent) Registration No. (Attorney/Agent) Telephone 650-564-5171							1809	750	2809	375				I rejection	
1204 84 2204 42 ** Reissue independent claims over original patent solution over original patent solution of a design application of a design application substitution of a design application of a design application substitution of a design application substitution of a design application of a				•			1810	750	2810	375	•	•	. ,,	to be	
1205 18 2205 9 ** Reissue claims in excess of 20 and over original patent SUBTOTAL (2) (\$) 504.00 **or number previously paid, if greater; For Reissues, see above SUBMITTED BY Registration No. (Attorney/Agent)		2204	42			t claims					exami	ned (37 C	FR 1.129(b))	
and over original patent SUBTOTAL (2) (\$) 504.00 **or number previously paid, if greater; For Reissues, see above SUBMITTED BY Registration No. (Attorney/Agent)	4005 10		_	•	•									` ,	
**or number previously paid, if greater; For Reissues, see above	1205 18	2205	9				1802	900	1802	900				ination	
**or number previously paid, if greater; For Reissues, see above Reduced by Basic Filing Fee Paid SUBTOTAL (3) (\$) 930.00 SUBMITTED BY (Complete (#applicable) Name (Print/Type) Robert R. Neller (Attorney/Agent) 46,950 Telephone 650-564-5171			SURT	OTAL (2)	(\$)	504 00	Other	fee (sp	ecify) _						
Name (Print/Type) Robert R. Neller Registration No. (Attorney/Agent) 46,950 Telephone 650-564-5171						*Red	*Reduced by Basic Filing Fee Paid SUBTOTAL (3) (\$) 930.0					930.00			
Robert R. Neller (Attorney/Agent) 46,950 relephone 650-564-51/1	SUBMITTED BY											(Complete (if applicable)		
	Name (Print/Type) Robert R. Neller							Pogiatratian No.				650-564-51	171		
	Signature Hoher & Heller														

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

This collection of information is required by 37 CFR 1.17 and 1.27. Information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

PTO/SB/05 (08-03)

Approved for use through 07/31/2006. OMB 0651-0032

U.S. Patent and Trademark Office. U.S. DEPARTMENT OF COMMERCE Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB of

UTILITY PATENT APPLICATION **TRANSMITTAL**

(Only for new nonprovisional applications under 37 CFR 1.53(b))

period of a seriod of the seri					
Attorney Docket No.	AR02766USACON2				
First Inventor	Atul D. AYER				
Title	See 1 in Addendum				
Express Mail Label No.	EV 324 303 928 US				

APPLICATION ELEMENTS See MPEP chapter 600 concerning utility patent application contents.	ADDRESS TO: Mail Stop Patent Application Commissioner for Patents P.O. Box 1450 Alexandria VA 22313-1450						
1. X Fee Transmittal Form (e.g., PTO/SB/17) (Submit an original and a duplicate for fee processing) Applicant claims small entity status. See 37 CFR 1.27. 3. X Specification [Total Pages 24] (preferred arrangement set forth below) - Descriptive title of the invention - Cross Reference to Related Applications - Statement Regarding Fed sponsored R & D - Reference to sequence listing, a table, or a computer program listing appendix - Background of the Invention - Brief Summary of the Invention - Brief Description of the Drawings (if filed) - Detailed Description - Claim(s) - Abstract of the Disclosure 4. X Drawing(s) (35 U.S.C. 113) [Total Sheets 2] 5. Oath or Declaration [Total Sheets 4] a. Newly executed (original or copy) b. X Copy from a prior application (37 CFR 1.63(d)) (for continuation/divisional with Box 18 completed) i. DELETION OF INVENTOR(S) Signed statement attached deleting inventor(s) name in the prior application, see 37 CFR 1.63(d)(2) and 1.33(b). 6. Application Data Sheet. See 37 CFR 1.76	7. CD-ROM or CD-R in duplicate, large table or Computer Program (Appendix) 8. Nucleotide and/or Amino Acid Sequence Submission (if applicable, all necessary) a. Computer Readable Form (CRF) b. Specification Sequence Listing on: i. CD-ROM or CD-R (2 copies); or ii. Paper c. Statements verifying identity of above copies ACCOMPANYING APPLICATION PARTS 9. Assignment Papers (cover sheet & document(s)) 10. 37 CFR 3.73(b) Statement Power of (when there is an assignee) Attorney 11. English Translation Document (if applicable) 12. Information Disclosure Copies of IDS Statement (IDS)/PTO-1499 Citations 13. X Preliminary Amendment 14. Return Receipt Postcard (MPEP 503) (Should be specifically itemized) 15. Certified Copy of Priority Document(s) (if foreign priority is claimed) Nonpublication Request under 35 U.S.C. 122 (b)(2)(B)(i). Applicant must attach form PTO/SB/35 or its equivalent. 17. X Other: Revocation and Power of						
18. If a CONTINUING APPLICATION, check appropriate box, and supply the requisite information below and in the first sentence of the specification following the title, or in an Application Data Sheet under 37 CFR 1.76:							
Continuation Divisional Continuation-in-part (CIP) of prior application No.: 09/588,800 Prior application information: Examiner CHANNAVAJJALA, L.S. Art Unit: 1615 For CONTINUATION OF DIVISIONAL APPS only; The entire disclosure of the prior application, from which an oath or declaration is supplied under Box 5b, is considered a part of the disclosure of the accompanying continuation or divisional application and is hereby incorporated by reference. The incorporation can only be relied upon when a portion has been inadvertently omitted from the submitted application parts.							
	DENCE ADDRESS						
X Customer Number: 27777	OR Correspondence address below						
Name							
Address							
	State Zip Code						
Country Te	elephone Fax						
Name (Print/Type) Roberts R. Netler Signature / Skul / Mellar	Registration No. (Attorney/Agent) 46,950						
Signature Skut / //ella	Date 09/12/2003						

This collection of informetion is required by 37 CFR 1.53(b). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop Patent Application, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Addendum

1. THERAPEUTIC COMPOSITION AND DELIVERY SYSTEM FOR ADMINISTERING DRUG